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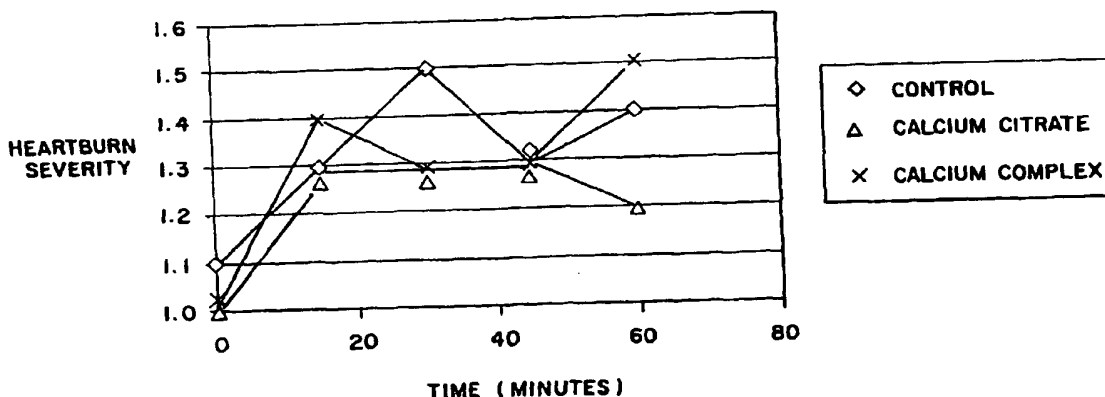
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(54) Title: ORANGE JUICE FOR THE REDUCING OF HEARTBURN

HEARTBURN RATING OVER TIME FOR NFC OJ PRODUCTS



(57) Abstract: Reducing heartburn episodes is achieved in individuals having an orange juice intolerance or food allergy. The orange juice product has a low titratable acidity which combines with a condition resulting after addition of a calcium source such as a calcium citrate source. Individuals prone to orange juice induced heartburn episodes experience a reduced incidence of these heartburn episodes.

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## ORANGE JUICE FOR REDUCING HEARTBURN

### Description

#### Background of the Invention

#### Field of Invention

[0001] This invention relates to approaches for reducing heartburn episodes when an individual having an orange juice intolerance ingests orange juice according to the invention. The invention is achieved without any substantial negative impact on orange juice flavor or other important attributes. The heartburn reduction is achieved by orange juice which combines the features of being of a lower acid type while incorporating a calcium source such as in the form of a calcium citrate source.

#### Description of Related Art

[0002] Numerous individuals have been known to experience negative effects upon ingesting different foods. A true food allergy occurs when the immune system of the individual overreacts to certain proteins in food. It is believed that hundreds of food ingredients can provoke an allergic reaction. Typical foods in this regard are nuts, peanuts, milk, eggs, fish, shellfish, soybeans and wheat. Foods such as these can lead to symptoms including nausea, hives, skin rash, nasal congestion, wheezing, and the like. However, most unpleasant reactions to food are caused not by allergies but by intolerances, which tend to be less severe than true food allergies. Typical in this regard are lactose

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intolerance, sulfite intolerance and intolerance to monosodium glutamate, red wine, chocolate and food coloring agents. Another intolerance of some frequency is manifested by gastral distress and/or digestive difficulties which certain individuals experience shortly after ingesting orange juice products.

[0003] In some circles, it is generally assumed that the relatively high acidity of orange juice products is a primary contributor to these negative or unpleasant experiences with orange juice products for a small percentage of the population. For example, Kligerman et al U.S. Patents No. 5,665,415 and No. 5,869,119, incorporated herein by reference, suggest that acidic foods or beverages such as coffee and other beverages can be combined with calcium glycerophosphate so as to raise the pH of the food or beverage by at least 0.5 pH units, such as to a pH of greater than 5.4, which typically is pH higher than desirable for superior tasting orange juice. This pH adjustment is said to reduce the tendency of the food or beverage to cause heartburn and other esophageal and/or gastrointestinal distress. This approach generally follows the conventional wisdom that ingesting antacids treats heartburn by helping to neutralize stomach acid. This approach suggests, in general, raising the pH of the food or beverage to well above 5.

[0004] Other approaches have suggested acid reduction for relieving symptoms such as the burning, painful sensation of heartburn. Included is Georgiades et al. U.S. Patent No. 5,762,962, incorporated herein by reference. This patent is directed to antacid pharmaceutical compositions comprising a combination of calcium salts. Another pharmaceutical is found in Korn et al. U.S. Patent No. 5,989,588 which suggests administering to a patient for preventing heartburn a composition having

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a pharmaceutically effective amount of an H<sub>2</sub> antagonist such as famotidine. These antacid approaches administer tablets in a manner customary for over-the-counter or pharmaceutical antacid administration.

[0005] In addition it is well-known that beverages such as orange juice can be supplemented with calcium with the objective of addressing inadequate calcium in the diets of certain individuals, especially in connection with combating osteoporosis. Numerous approaches have been proposed or implemented in this regard. Included is the technology in patents such as Meyer et al U.S. Patent No. 5,474,793, Camden et al U.S. Patent No. 5,225,221, and Heckert U.S. Patent No. 4,722,847, each incorporated hereinto by reference. These take the approach of adding to fruit juices a source of calcium together with a mixture of citric acid and malic acid. A complex solution is formed and mixed with the juice.

[0006] Another calcium fortified beverage approach, this one being for shelf-stable beverages, is found in Keating U.S. Patents No. 5,500,232 and 5,834,045, incorporated hereinto by reference. These add an acidulant and a source of calcium hydroxide and calcium glycerophosphate.

[0007] These various approaches do not directly address the problem faced by individuals who wish to alleviate discomfort generally falling under the category of heartburn and which can be associated with drinking orange juice. Previous approaches focus on reducing acidity, either within the juice itself, or by administering antacid tablets in an effort to combat acidity within the digestive tract of the individual drinking the orange juice. Approaches heretofore have not satisfactorily arrived at orange juice products themselves which directly address the incidence of heartburn episodes in those

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individuals who have an orange juice intolerance, insensitivity or allergy. There accordingly is a need for an approach which is more effective than acidity reduction and that is more convenient and self-contained than is the antacid tablet approach.

#### Summary of the Invention

[0008] In accordance with the present invention, orange juice itself is provided which reduces the incidence of heartburn episodes in individuals having orange juice intolerance. An orange juice supply is provided and/or modified to be a low-acid orange juice supply having a titratable acid content of not greater than about 0.6 weight percent based upon the total weight of the juice product. A calcium additive such as a calcium citrate source is added to the low-acid orange juice supply so that the calcium concentration within the orange juice product is greater than 0.04 weight percent, based upon the total weight of the orange juice product. Heartburn episodes are reduced for an individual having orange juice intolerance when compared with the incidence of heartburn episodes by that same individual ingesting the orange juice supply which does not include these characteristics.

[0009] A general object of the present invention is to provide a method and product for reducing the incidence of heartburn episodes in an individual having an orange juice intolerance.

[0010] Another object of the present invention is to provide an approach for reducing heartburn episodes by avoiding the episodes, rather than by administering a treatment agent to the individual, by providing an orange juice product which does not antagonize the individual so that heartburn symptoms develop.

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[0011] Another object of this invention is to provide an improved method and product for safe ingestion of orange juice without experiencing gastrointestinal discomfort.

[0012] Another object of the present invention is to provide a modified orange juice supply having a combination of low titratable acidity and calcium buffering characteristics which produce a situation by which heartburn discomfort by orange juice ingestion is lessened.

[0013] Other objects and advantages of the present invention will be understood from the following description according to preferred embodiments of the present invention, relevant information concerning which is shown in the accompanying drawings.

#### Brief Description of the Drawings

[0014] FIG. 1 is a plot of data of heartburn rating over time collected during evaluation of three different formulations of Not From Concentrate (NFC) orange juice.

[0015] FIG. 2 is a plot of data of heartburn ratings over time collected during evaluation of certain From Concentrate (FC) orange juice products.

#### Description of the Preferred Embodiments

[0016] Orange juice products are provided which have been found to alleviate gastrointestinal distress in individuals which tend to have negative or uncomfortable gastrointestinal experiences upon ingesting orange juice. Such individuals experience post-ingestive symptoms of so-called acid reflux or heartburn. Included in the orange juice products, which are included as an aspect of the invention, is an orange juice supply having low-acid characteristics. The orange juice supply also is further

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modified in a manner which combines with the low acidity to achieve superior distress relief.

[0017] Referring to the low-acid component of the invention, this is expressed in terms of titratable acidity. While the concept of titratable acidity is well-known to those in the art, the preferred test for measuring titratable acidity is the standard method of titration of citric acid with sodium hydroxide.

[0018] Although the titratable acidity of orange juice will vary somewhat depending upon the fruit cultivar from which the juice is extracted and the time of the year within the growing season for each cultivar, historically it can be noted that titratable acidity typically varies between about 0.62 and 0.82 for Not From Concentrate orange juices. In most instances, normal titratable acidity values are between about 0.65 and 0.8 for a typical orange juice supply before any processing. In accordance with this invention, the finished juice product will have a titratable acidity of not greater than about 0.6 weight percent. Typically, the titratable acidity will be between about 0.5 and about 0.6 weight percent. An especially advantageous target acidity level is about 0.55 weight percent.

[0019] In one aspect of the low-acid characteristic of the invention, the orange juice supply is modified (or selected) without carrying out any specific deacidification process. In accordance with this aspect, at least two different approaches can be practiced. In one approach, the fruit going into the extractor is selected so as to provide juice modified to have the desired titratable acidity. In another approach, the juice stream from the extractor is segregated so as to separate the higher acidity flows from lower acidity flows to provide the modified juice. This typically will

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include monitoring titratable acidity in the flows so as to provide the modifying of an orange juice supply having the titratable acidity needed to achieve the desired low-acid characteristic in the orange juice product. For example, a Not From Concentrate orange juice can be sourced at a desired titratable acidity, such as 0.58, according to this aspect of the low-acid feature.

[0020] Another aspect for modifying the orange juice supply to a low-acid orange juice supply is by proceeding with deacidification of an orange juice supply which has a titratable acidity greater than the titratable acidity to be provided. The deacidification of juice products is well-known in the art. A preferred deacidification approach utilizes ion exchange equipment and procedures. Contact between the juice stream and the ion exchange resin basic moieties reduces the acid level and titratable acidity of the juice contacted by the ion exchange resin bed. Any other suitable deacidification approach likewise can be practiced provided the selected technology achieves the desired titratable acidity level.

[0021] It is generally preferred that any of these methods for modifying the orange juice supply to a low-acid orange juice supply, whether using deacidification techniques or not, is carried out prior to additional modification of the juice supply. Generally, this modification is a calcium addition such as a calcium citrate source addition.

[0022] Adding a calcium citrate source to the low-acid orange juice supply provides a calcium concentration within the orange juice that is greater than 0.04 weight percent, based upon the total weight of the orange juice. The Ca levels are measured by a standard wet chemistry analysis of titration with ethylene diaminetetracetic acid. While not wishing to be bound by any particular



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mechanism for achieving the objects herein, it is believed that the calcium citrate source addition has at least two advantageous effects.

[0023] One effect is that the calcium source such as a calcium citrate source apparently lowers somewhat the titratable acidity. This can be considered as a mechanism which, together with the low-acid modifying approach, combine to achieve the target low titratable acidity which is selected for the product. For example, an orange juice supply which has a borderline or a slightly elevated titratable acidity can be brought within the needed titratable acidity range by the calcium citrate source addition.

[0024] Another mechanism which is believed to occur with the addition of a calcium source such as a calcium citrate source can be loosely characterized as assisting in negating the distress-aggravating effects of the citrus oil content of the juice supply. This is believed to be particularly evident when the citrus oil content of the orange juice supply being used is not lowered substantially by either formulation or processing.

[0025] The calcium citrate source typically is provided as a powdered tetrahydrate. Calcium citrate preferably is provided as tricalcium citrate tetrahydrate. It will be appreciated that most orange juice sources already have a relatively low quantity of calcium. The concentration of calcium is increased by the calcium citrate source addition such that the concentration of calcium within the orange juice product is greater than 0.04 weight percent and equal to or less than 0.2 weight percent. It will be appreciated that calcium levels within higher portions of this range can produce juice products which are characterized as containing a calcium supplement. It is not the objective of the calcium citrate source addition

to add calcium citrate to levels at or in excess of that which a claim for a calcium supplemented juice can be made. Rather, it is contemplated that calcium levels can be at lower levels. Thus, the advantages of the calcium citrate source addition according to this invention typically are achieved without any need to be as high as that needed to provide a juice which can be labeled as a calcium supplemented orange juice.

[0026] In fact, it is generally preferred that the calcium citrate source addition be at a level below that at which taste or other sensory parameters will be affected negatively or will otherwise deviate from a chosen norm. Levels above about 0.065 weight percent calcium in the orange juice product tend to exhibit these effects. Accordingly, when these effects are to be avoided, the calcium content should be below about 0.07 weight percent, more comfortably below about 0.06 weight percent. An especially preferred calcium content range for products according to the invention for many juice sources is between above 0.04 weight percent and below 0.05 weight percent.

[0027] Addition of the calcium citrate source into the orange juice supply can be carried out by any conventional means of adding a powdered or particulate product and which is suitable for industrial-scale operations. Typically, a conventional dry solids mixing system is adequate. Generally, there is no need to prepare any calcium solution, such as one that is made up for the addition of a liquid type of calcium additive as a premix or into the orange juice stream.

[0028] Without wishing to be bound by any particular theory, it is presently believed that the citrus oil content of an orange juice product is a primary contributor the distress experienced by those individuals

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having an orange juice intolerance or food allergy, and the calcium citrate source effectively reduces this negative impact. Citrus oil is generally understood in the art as being the component of citrus juice at a concentration measured by the Scott oil method, which is well-known in the citrus juice art. Typically, the Scott oil method detects and measures the effects of compounds which add bromine across double bonds. Typical citrus oil content is primarily a terpene content which originates to a large extent from citrus peel. A typical major terpene in orange juice is d-limonene.

[0029] Referring particularly to the method for reducing the incidence of heartburn episodes or other distress experienced by individuals having an orange juice intolerance or allergy, an orange juice supply first is provided. This supply is modified either by selecting an orange juice supply having the low-acid characteristics discussed herein and/or by deacidifying the orange juice supply. A low-acid orange juice supply thus is provided. Adding a calcium source such as a calcium citrate source to the orange juice supply is carried out. A typical orange juice product thus prepared has a pH between about 3.7 and 4.4.

[0030] The resulting orange juice product has characteristics which safeguard and/or insulate the individual from heartburn causation so as to reduce the incidence of heartburn episodes. More particularly, the method achieves a reduction in the incidence of heartburn episodes in an individual having difficulties with orange juice ingestion, this reduction being when compared with the incidence of heartburn episodes by that individual ingesting an orange juice supply which does not have the characteristics of the juice described herein.

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[0031] This method achieves these effects without significantly detrimentally affecting the sensory attributes of the citrus juice. These sensory attributes include taste and especially mouthfeel of the juice. In most instances, the juice products carrying out the method exhibit a mouthfeel and/or taste which is recognized as being smoother than orange juice not having the characteristics disclosed herein.

[0032] Studies were undertaken in order to evaluate the heartburn episode reduction of the method aspects of the invention, as reported in the following Examples.

#### EXAMPLE 1

[0033] Three orange juice products of the not-from-concentrate (NFC) type were prepared in illustrating the invention. They were formulated as follows. Reported percents are rounded to 0.001 percent.

[0034] The Control product was a simulated product of 99.9 weight percent of this NFC product and 0.01 volume percent added citrus oil. This NFC control had a typically normal oil level of 0.036 volume percent. This and all other percent concentrations herein are based upon the total volume or weight of the orange juice product, unless otherwise specified. The titratable acidity of the control was 0.063 weight percent, and the control was analyzed as having 11 mg of calcium per 100mL of juice (about 0.01 weight percent). This Control was heat pasteurized in accordance with usual industry practices. All of the products of this Example were pasteurized and held refrigerated in bottles until use.

[0035] The other two test products were prepared from separate portions of the NFC component of the Control. The test juices were formulated so as to prepare juice products based upon a 100 weight percent formulation.

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[0036] For example, one of the test products was comprised of 99.19 weight percent of the NFC juice, 0.01 volume percent of the same type of added citrus oil, 0.80 weight percent of a so-called calcium citrate malate complex. This is identified as the Calcium Citrate Malate Complex test juice NFC product. It analyzed as having a titratable acidity of 0.71 weight percent, a calcium content of 150.6 mg per 100 ml of juice (about 0.14 weight percent), and 0.032 volume percent citrus oil. No flavor oil was added to the Control NFC juice component. This product formulation included blending appropriate amounts of citric acid, malic acid and calcium hydroxide into the Control NFC.

[0037] The remaining test juice is identified as the Calcium Citrate test juice NFC product. This was formulated from 99.33 weight percent of the NFC juice component, 0.01 volume percent of the added citrus oil, and 0.66 weight percent of tricalcium citrate tetrahydrate as the calcium source. This test product had a titratable acidity of 0.58 weight percent, a calcium concentration of 172.3 mg per 100 ml of juice (about 0.16 weight percent), and 0.033 volume percent of the citrus oil.

[0038] Healthy male and female adult volunteer subjects were screened for their ability to perceive digestive difficulties with orange juice. Each recruit participated in four screening sessions. After an overnight fast, each subject was provided with 8 ounces of either orange juice or a placebo beverage (apple juice) in a styrofoam cup having an opaque lid and straw to obscure visual difference. Each subject was requested to rate post-ingestive symptoms over one hour at 15 minute intervals. On three of the four screening occasions, the screening beverage was regular orange juice, and on the other occasion, the placebo was the beverage ingested.

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Individuals who reported symptoms for two of the three orange juice trials and had no reaction to the placebo were admitted to the study. The study had 14 subjects.

[0039] The three NFC juice products of this Example were evaluated in duplicate during ten sessions spread over ten days. The qualified subjects recorded their reactions (self-perceived) to each product when tested by placing a mark on a generic human figure representing the area of discomfort for that subject during that test event. At that time, each subject gave the designated symptom a numerical rating. Ratings were recorded when the subjects first ingested each sample and at 15, 30, 45, and 60 minute intervals.

[0040] Table I provides chemical analyses of each of the three products which were ingested by the subjects in this study. Also reported is the Mean Response of heartburn symptoms. This illustrates the severity of heartburn symptoms or episodes of all of the test subjects for each of the test orange juice products. Means having the same letter are not significantly different at  $P < 0.05$ , according to standard least significant differences (LSD) analysis. From these results, the following observation conclusions are reached.

[0041] The Calcium Citrate NFC orange juice products showed a decisive statistical significant difference in reduced heartburn symptoms when compared with the Control. The Calcium Citrate Malate Complex having a relatively high acid percentage showed no difference in heartburn response from the Control NFC orange juice.

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TABLE I

	Control	Calcium Citrate Malate Complex	Calcium Citrate
Brix	11.7	12.4	12.1
Acid, %	0.63	0.71	0.58
Ratio	18.54	17.51	20.8
pH	3.92	4.09	4.18
Bottom Solids	13.0	13.0	11.0
Oil, %	0.036	0.032	0.033
Calcium, mg/100 mL	11.0	150.6	172.3
Mean Response	1.30 ab	1.30 ab	1.21c

[0042] In order to illustrate the effect on heartburn symptoms for these NFC orange juice products, data in this regard are plotted on FIG. 1. This plot tracks the heartburn rating versus minutes after ingestion. It is noted that the Calcium Citrate Malate Complex NFC juice experienced somewhat greater heartburn severity at 15 minutes and spiked at 60 minutes, while the initial severity of heartburn symptoms for the Calcium Citrate NFC orange juice formulation was extremely low initially and never surpassed the 15 minute heartburn severity level. The Control product showed a particularly high increase in severity at 30 minutes and again increased somewhat at 60 minutes.

#### EXAMPLE 2

[0043] Three From Concentrate orange juice products were formulated as follows. In these, all percents were rounded to 0.01%.

[0044] A Control FC orange juice was prepared by combining 17.64 weight percent orange juice concentrate (65 brix) with 82.33 weight percent water and 0.03 volume

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percent added citrus oil. The Control FC orange juice product was a conventional product produced by diluting no-oil added orange juice concentrate with water (to 12.2 brix) and adding orange oil to a concentration of 0.025 volume percent according to the Scott oil method.

[0045] A Calcium Citrate FC orange juice product was prepared from 17.49 weight percent of the same concentrate, 81.66 weight percent water, 0.03 volume percent added citrus oil, and 0.82 weight percent of tricalcium citrate tetrahydrate.

[0046] A No Solids FC orange juice was prepared by combining 17.64 weight percent of the concentrate with 82.33 weight percent of water, and this was centrifuged to remove bottom solids until a "0" solids analysis was achieved. Thereafter, citrus oil was added at a level of 0.03 volume percent.

[0047] The clinical trial procedures discussed in accordance with Example 1 were followed. First, screening was conducted as in Example 1. In this study 20 subjects participated. These FC orange juice products were evaluated in duplicate over eight test sessions in random order, the sessions being separated by at least one day. The qualified subjects recorded their reactions in the manner of Example 1.

[0048] The relevant chemical parameters and heartburn response ratings at one hour after ingestion of each type of product are reported in Table II. These responses are reported as Mean Response values.



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TABLE II

	Control	No Solids	Calcium Citrate
Brix	12.2	12.2	12.8
Acid, %	0.66	0.66	0.60
Ratio	18.41	18.55	21.33
pH	3.90	4.01	4.21
Bottom Solids	10.0	0.0	10.0
Oil, %	0.025	0.016	0.025
Calcium, mg/100 mL	9.0	8.9	155.5
Vitamin C, mg./100 mL	49.3	41.6	36.0
Limonene, ppm	113	67	111

Mean

Response

1.6 a

1.5 ab

1.3 b

[0049] The Mean Response values reported in Table II are at one hour after ingestion. Means having the same letter are not significantly different at  $\alpha = 0.01$ . A standard LSD analysis was used. These Mean Responses indicate that the Calcium Citrate FC orange juice product reported statistically significant reduced heartburn symptoms relative to the Control FC product. This benefit was attained in an FC orange juice having a high oil content, the oil content of the Calcium Citrate FC product being as high as that of the Control. These Mean Responses also indicate that the No Solids FC product was not associated with a statistically significant reduced heartburn result, even though limonene levels were about half of the other products and there were no solids. Of course, no calcium source was added.

[0050] FIG. 2 provides an indication of the consistency of the heartburn severity reduction over the rating time intervals for the Calcium Citrate product versus the Control FC product.

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[0051] It will be understood that the embodiments of the present invention which have been described are illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

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Claims

1. A method for reducing the incidence of heartburn episodes in an individual having an orange juice intolerance, comprising the steps of:

providing an initial orange juice supply;

modifying said initial orange juice supply to a low-acid orange juice supply having a low titratable acid content;

adding a calcium citrate source to said low-acid orange juice supply thereby increasing the calcium content of the low-acid orange juice and thereby providing an orange juice having heartburn-safeguarding characteristics, said orange juice having heartburn-safeguarding characteristics being an orange juice product having:

(a) a titratable acidity which is not greater than about 0.6 weight percent, based upon the total weight of the orange juice product, and

(b) a calcium concentration which is greater than 0.04 weight percent, based upon the total weight of the orange juice product; and

ingesting said orange juice product having heartburn-safeguarding characteristics by an individual having an orange juice intolerance such that the incidence of heartburn episodes by that individual is reduced over the incidence of heartburn episodes by said individual ingesting said initial orange juice supply.

2. The method of claim 1, wherein the low-acid orange juice supply of said adding step has a titratable acidity of not greater than about 0.6 weight percent, based upon the total weight of the orange juice supply.

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3. The method of claim 1, wherein the orange juice product having heartburn-safeguarding characteristics of said ingesting step has a titratable acidity of between about 0.5 and about 0.6 weight percent, based upon the total weight of the orange juice supply.

4. The method of claim 1, wherein the low-acid orange juice supply of said adding step has a titratable acidity of between about 0.5 and about 0.6 weight percent, based upon the total weight of the orange juice supply.

5. The method of claim 1, wherein the adding step adds tricalcium citrate tetrahydrate as the calcium citrate source.

6. The method of claim 1, wherein the adding step adds the calcium citrate source as dry solid particulates into the orange juice supply.

7. The method of claim 5, wherein the tricalcium citrate tetrahydrate is added by said adding step as dry solid particulates.

8. The method of claim 1, wherein after said adding step the calcium concentration of the orange juice product having heartburn-safeguarding characteristics is not greater than about 0.2 weight percent, based upon the total weight of the orange juice.

9. The method of claim 1, wherein said modifying step includes reducing the titratable acidity of the initial orange juice supply to provide the low-acid orange juice supply.

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10. The method of claim 1, wherein said modifying step includes selecting an orange source to have the low titratable acid content.

11. A method for reducing the incidence of heartburn episodes in an individual having an orange juice intolerance, comprising the steps of:

providing an initial orange juice supply;  
modifying said initial orange juice supply to a low-acid orange juice supply having a low-acid condition;  
adding to said orange juice supply a calcium source;

said low-acid condition and said calcium source combine to provide an orange juice having heartburn-safeguarding characteristics, said orange juice having heartburn safeguarding characteristics being an orange juice product having:

(a) a titratable acidity which is not greater than about 0.6 weight percent, based upon the total weight of the orange juice product, and

(b) a concentration of calcium in said orange juice supply which is greater than 0.04 weight percent, based upon the total weight of the orange juice supply;  
and

ingesting said orange juice product having heartburn-safeguarding characteristics by an individual having an orange juice intolerance such that the incidence of heartburn episodes by that individual is reduced over the incidence of heartburn episodes by said individual ingesting said initial orange juice supply.

12. The method of claim 11, wherein the low-acid orange juice supply of said adding step has a titratable

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acidity of not greater than about 0.6 weight percent, based upon the total weight of the orange juice supply.

13. The method of claim 11, wherein the orange juice product having heartburn-safeguarding characteristics of said ingesting step has a titratable acidity of between about 0.5 and about 0.6 weight percent, based upon the total weight of the orange juice supply.

14. The method of claim 11, wherein the low-acid orange juice supply of said adding step has a titratable acidity of between about 0.5 and about 0.6 weight percent, based upon the total weight of the orange juice supply.

15. The method of claim 11, wherein the adding step adds tricalcium citrate tetrahydrate as the calcium source.

16. The method of claim 11, wherein the adding step adds the calcium source as dry solid particulates into the orange juice supply.

17. The method of claim 15, wherein the tricalcium citrate tetrahydrate is added by said adding step as dry solid particulates.

18. The method of claim 11, wherein after said adding step the calcium concentration of the orange juice product having heartburn-safeguarding characteristics is not greater than about 0.2 weight percent, based upon the total weight of the orange juice.

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19. The method of claim 11, wherein said modifying step includes reducing the titratable acidity of the initial orange juice supply to provide the low-acid orange juice supply.

20. The method of claim 11, wherein said modifying step includes selecting an orange source to have the low titratable acid content.

21. An orange juice product produced in accordance with the method of claim 1, wherein the orange juice product has said heartburn-safeguarding characteristics.

22. An orange juice product produced in accordance with the method of claim 11, wherein the orange juice product has said heartburn-safeguarding characteristics.

23. An orange juice product having heartburn safeguarding characteristics when ingested by an individual having an orange juice intolerance, comprising: a low-acid orange juice product containing a calcium citrate source from tricalcium citrate tetrahydrate, the orange juice product having:

(a) a titratable acidity which is not greater than 0.6 weight percent, based upon the total weight of the orange juice product;

(b) a tricalcium citrate tetrahydrate component such that the calcium concentration is greater than 0.04 weight percent, based upon the total weight of the orange juice product; and

(c) heartburn-safeguarding characteristics when ingested by an individual having an orange juice

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intolerance such that the incidence of heartburn episodes by said individual ingesting another orange juice product having a titratable acidity greater than 0.6 weight percent, based upon the total weight of the product, and having no said tricalcium citrate tetrahydrate component.

24. The product of claim 23, wherein the orange juice product having heartburn-safeguarding characteristics has a titratable acidity of between 0.5 and 0.6 weight percent, based upon the total weight of the orange juice product.

25. The product of claim 23, wherein the calcium concentration of the orange juice product is not greater than 0.2 weight percent, based upon the total weight of the orange juice product.



FIG.1

HEARTBURN RATING OVER TIME FOR NFC OJ PRODUCTS

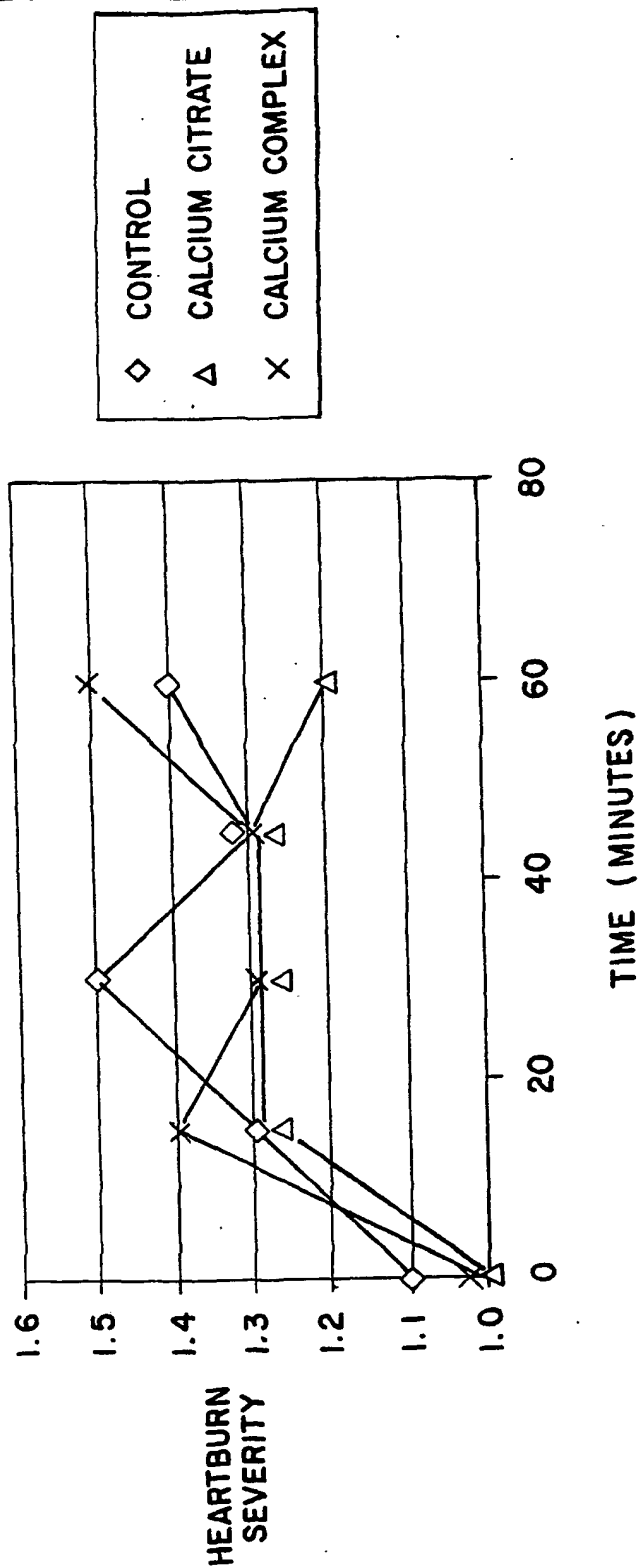
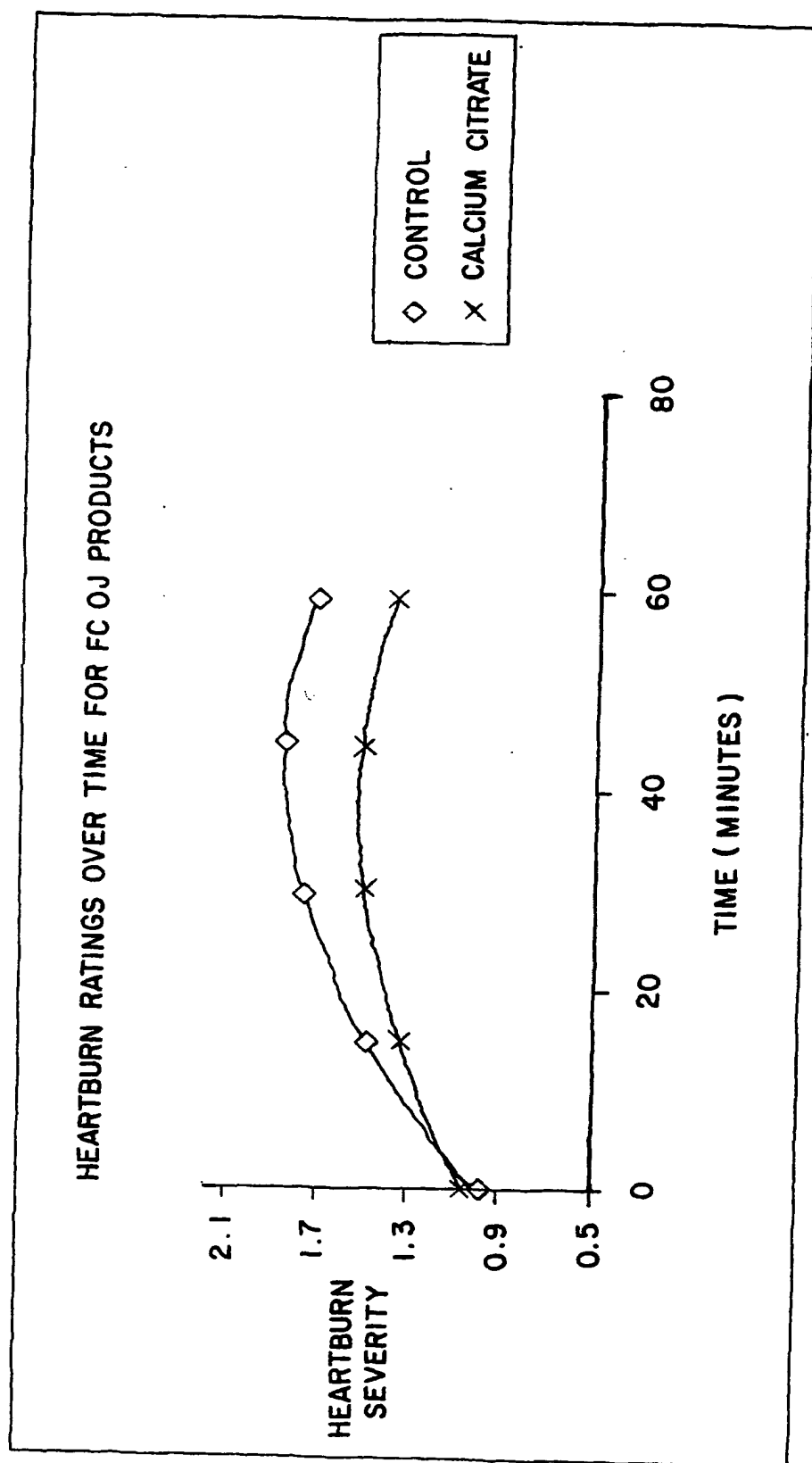


FIG. 2



# ATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>0883-0120</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 02/ 13425</b>	International filing date (day/month/year) <b>29/04/2002</b>	(Earliest) Priority Date (day/month/year) <b>03/05/2001</b>
Applicant <b>TROPICANA PRODUCTS, INC.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

#### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).  
 3. ☐ **Unity of invention is lacking** (see Box II).

#### 4. With regard to the **title**,

- ☐ the text is approved as submitted by the applicant.  
☒ the text has been established by this Authority to read as follows:

**ORANGE JUICE FOR THE REDUCING OF HEARTBURN**

#### 5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

#### 6. The figure of the **drawings** to be published with the abstract is Figure No.

- ☒ as suggested by the applicant.  
☐ because the applicant failed to suggest a figure.  
☐ because this figure better characterizes the invention.

1  
☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/13425

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A23L2/00 A23L2/02 A23L2/52 A23L2/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, MEDLINE, WPI Data, PAJ, FSTA

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DATABASE BIOSIS 'Online!  BIOSCIENCES INFORMATION SERVICE,  PHILADELPHIA, PA, US; 1995  FELDMAN MARK ET AL: "Relationships between  the acidity and osmolality of popular  beverages and reported postprandial  heartburn."  Database accession no. PREV199598096353  XP002206238  abstract  &amp; GASTROENTEROLOGY,  vol. 108, no. 1, 1995, pages 125-131,  ISSN: 0016-5085</p> <p style="text-align: center;">--- -/--</p>	1-25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*8\* document member of the same patent family

Date of the actual completion of the international search

16 July 2002

Date of mailing of the international search report

01/08/2002

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/13425

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DATABASE MEDLINE 'Online!  January 1982 (1982-01)  MOWSCHENSON P M ET AL: "Effect of  hyperparathyroidism and hypercalcemia on  lower esophageal sphincter pressure."  Database accession no. NLM7053653  XP002206239  abstract  &amp; AMERICAN JOURNAL OF SURGERY. UNITED  STATES JAN 1982,  vol. 143, no. 1, January 1982 (1982-01),  pages 36-39,  ISSN: 0002-9610</p>	1-25
A	<p>US 5 665 415 A (HARTZELL SARAH ET AL)  9 September 1997 (1997-09-09)  cited in the application  claims 1-5,9,11,14,15</p>	1-25
A	<p>US 4 919 963 A (HECKERT DAVID C)  24 April 1990 (1990-04-24)  column 11, line 45 -column 12, line 25;  claim 1</p>	1-25
A	<p>US 5 108 761 A (ANDON MARK B ET AL)  28 April 1992 (1992-04-28)  column 2, line 45 - line 66; claims;  examples</p>	1-25

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/13425

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5665415	A	09-09-1997	AU 715991 B2	17-02-2000
			AU 6507396 A	26-02-1997
			BR 9609876 A	23-03-1999
			CN 1194572 A ,B	30-09-1998
			EG 21702 A	27-02-2002
			EP 0849996 A1	01-07-1998
			IL 122986 A	13-08-2000
			JP 11514213 T	07-12-1999
			NZ 313085 A	28-10-1999
			WO 9704661 A1	13-02-1997
			US 5869119 A	09-02-1999
			ZA 9606241 A	19-03-1997
US 4919963	A	24-04-1990	US 4722847 A	02-02-1988
			AT 55042 T	15-08-1990
			AU 594271 B2	01-03-1990
			AU 7253387 A	12-11-1987
			CA 1325130 A1	14-12-1993
			DE 3764017 D1	06-09-1990
			DE 244903 T1	07-04-1988
			EG 18049 A	30-08-1991
			EP 0244903 A1	11-11-1987
			ES 2016336 T5	16-11-1999
			FI 872007 A ,B,	08-11-1987
			GR 3000729 T3	10-10-1991
			GR 3031471 T3	31-01-2000
			IE 60333 B	29-06-1994
			JP 2559732 B2	04-12-1996
			JP 63052864 A	07-03-1988
			KR 9604263 B1	30-03-1996
			MX 165456 B	11-11-1992
			PH 23972 A	23-01-1990
			PH 27164 A	02-04-1993
			PT 84820 A ,B	01-06-1987
			TR 24771 A	09-03-1992
US 5108761	A	28-04-1992	AT 130173 T	15-12-1995
			AU 3228299 A	05-08-1999
			AU 3285695 A	14-12-1995
			AU 708830 B2	12-08-1999
			AU 8314898 A	29-10-1998
			AU 8761591 A	28-04-1992
			DE 69114717 D1	21-12-1995
			DE 69114717 T2	15-05-1996
			EP 0551398 A1	21-07-1993
			HK 1006136 A1	12-02-1999
			MX 9101398 A1	05-06-1992
			NZ 240003 A	27-08-1996
			WO 9205711 A1	16-04-1992

Form PCT/ISA/210 (patent family annex) (July 1992)